19. A method of treating or reducing damage to th skin, wherein the damage is associated with a reduction or loss of skin barrier function, which comprises adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and about 0.1 to about 10.0 percent of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition, and applying said vehicle containing said mixture to the skin.

Please cancel claim 2.

REMARKS

The Examiner rejects Claims 1 to 12, and 16 to 20 under section §112, second paragraph for indefiniteness. In particular, Claim 1 is rejected because the phrase "effective amount" is unclear, and Claims 16 and 19 are rejected because the phrase "and applying said mixture to the skin is unclear, and finally Claim 18 is rejected for lack of antecedent basis. Claim 1 has been amended to clarify the meaning of "effective amount." Claim 18 has been amended to remove the typographical error, and antecedent basis is not present. With respect to Claim 16, Applicants are not sure where the source of confusion lies. The Examiner notes that it is not clear what mixture is applied to the skin, the mixture of cholesterol sulfate and amino sugar, or the mixture of the cholesterol sulfate and amino sugar with a vehicle. However, in claims 16 and 19 the "mixture" is added directly to a vehicle for application to the skin. Regardless of whether the mixture is applied to the skin with or without the vehicle, the term "mixture" is quite clear in this claim as being the mixture of the cholesterol sulphate and the amino sugar, and the mixture, with or without the vehicle, is applied to the skin in both cases. However, to add further clarification to the claim, Applicants amend the claim to indicate that both the mixture and the vehicle are applied to the skin.

The Examiner rejects Claims 1, 3, and 11 under 35 U.S.C. 102(b) as being anticipated by Ribier et al., U.S. Patent No. 5,925,364 ("the '364 reference"). The '364 reference discloses an emulsion composition that has a lamellar liquid crystal coating. The composition as described in the claims can include materials such as alkali metal salts of cholesteryl sulphate as the ionic amphilic lipid as one of the layers coating an active. Further, the composition can contain as a fatty substance a keratolytic agent. One of the many keratolytic agents listed is retinol and salicylic acid which the Examiner notes that these materials are known exfoliants. Therefore, according to the Examiner, the '364 reference has disclosed the present invention because the Examiner maintains that layered coatings such as the one described in the '364 reference constitute a mixture as described in the present invention based on the Examiner's broad approach to the term

"mixture." However, Applicants assert that the scope of the term is to be interpreted in view of how one of ordinary skill in the art would make such an interpretation. Applicants further assert that the Examiner has failed to demonstrate why or on what basis one of ordinary skill in the art would make any interpretation other than the term's ordinary meaning, and it is Applicants position that one of ordinary skill in the art would interpret the term mixture to be consistent with the use of the term in the present specification. Finally, even if the interpretation of one of ordinary skill in the art were to be inconsistent with the use of the term in the present invention, Applicants assert that the claims of the present invention and the terms used therein are to be read in light of the specification. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979, 34 USPQ2d 1321, 1329 (Fed. Cir. 1995)(en banc), aff'd, 517 U.S. 370, 38 USPQ2d 1461 (1996); *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994). Therefore, the ordinary meaning of the term mixture should be applied and as such one of ordinary skill in the art would find the mixture of the present invention distinguishable over compositions containing components separated by encapsulation or vesicles as disclosed in the cited prior art.

The Examiner rejects Claims 1 to 9 and 13 to 19 under 35 U.S.C. 103 as being unpatentable over Ribier et al, U.S. Patent No. 5,650,166 ("the '166 reference"). The '166 references teaches a moisturizing composition which comprises two separate and distinct dispersions, namely, a first and a second dispersion of lipid vesicles. The first lipid vesicle penetrates, according to the '166 reference, into the deep layers of the skin and contains at least one active. This action is, like the two dispersions themselves, separate from the action of the other dispersion, and therefore, is not a disclosure of the mixture of the present invention where the two components act together. Thus, as previously discussed, the '166 reference fails to teach or suggest a mixture of cholesterol sulphate and an exfoliant of the present invention, and therefore, the '166 reference also fails to teach or suggest the present invention. There is no teaching, suggestion or motivation in the art or the knowledge of one of ordinary skill in the art to support the assertion that mixing components is broadly equivalent to or includes encapsulating components, or any other ordered arrangement of separately acting components. In the present action, the Examiner adds a broad interpretation of the term "add" to mean any variety of mixing steps. Again, there is no basis for such a broad reading of the term. If such a broad meaning applied to these or any other terms, vocabulary would be a limited subject as there would be no need for other specific words to describe in the case of the cited prior art processing steps for encapsulation or creation of two dispersions of vesicles. The '166 reference suggests separately acting dispersions of lipid vesicles, and in no way suggests the mixture of the present invention.

The claims of the present invention have been previously amended such that the mixture of cholesterol sulfate and exfoliant, N-acetyl glucosamine is added directly to a pharmaceutical or cosmetically acceptable vehicle. This is also not taught or suggested by the '166 reference which only discloses the use of these ingredients to form lipid vesicles, where the discrete layers are formed and the ingredients are physically separated by being present in different layers. There is no mixing of these ingredients, and the vesicles, not the ingredients themselves, are contained in a medium as taught at column 8, lines 32 to 35. This is especially true for N-acetylglucosamine (NADG) as the '166 reference teaches that the NADG is encapsulated within the lipid vesicle. Therefore, even though as the Examiner points out the vesicle is added to a phase, because the NADG is inside the vesicle, it is not possible for NADG, *per se*, to be added directly to the vehicle. The NADG stays separated from the vehicle by virtue of the encapsulation.

The teachings of the '166 reference are contrary to the present invention because with the mixture of NADG and cholesterol sulfate there is no separation between the two components or the vehicle. The NADG in the present invention is directly added to the vehicle as a part of the mixture with cholesterol sulfate. Thus, since the '166 reference fails to teach an NADG added directly to the vehicle, there is no teaching or suggestion of the mixture of cholesterol sulfate and an NADG added to the vehicle by the '166 reference. This demonstrates, therefore also, that the '166 reference, alone or in combination with Subbiah, U.S. Patent No. 6,150,381 ("the '381 reference") and Ichinose et al., U.S. Patent No. 5,702,691 ("the '691 reference), fails to render the present claims, as amended, obvious. Neither the '381 reference nor the '691 reference remedies the defect of the '166 reference in failing to teach or suggest either the mixture of the amino sugar and the cholesterol sulfate or the direct addition of the mixture to the vehicle by their teaching of sclareolide and white birch extract in a composition.

Finally, even if a *prima facie* case could be made, it would be rebutted by the surprising results of the present invention. As noted in the present specification at page 4, lines 1 to 12, it is unexpected to find that two opposing components would not cancel each other out when combined and added as a mixture to a composition. The Examiner responds that there are many ingredients in Example 1 of the present invention. Applicants have explained that most of these ingredients are part of the vehicle, and the remaining 8 as a whole are not central to the invention. The present invention centers around two ingredients, the cholesterol sulfate and the amino sugar, that although they have opposing activities, when added as a mixture to a pharmaceutical or cosmetic vehicle, their activity occurs in tandem, and can improve or maintain a healthy skin barrier. What is surprising is that their activity behaves in this manner without keeping them physically separate as disclosed

in the cited prior art by separate dispersions of vesicles or by encapsulation. This is a surprising and unexpected finding that is not taught or suggested by the cited references, alone or combined.

Because none of the cited references alone nor in combination would lead one of ordinary skill in the art to the compositions and methods of the present invention, a *prima facie* case of obviousness has not been established. Applicants request therefore, that the Examiner's rejection under §103 be withdrawn.

CONCLUSION

In view of the arguments presented above in the present submission, the claims are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date 02/05/03

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MARKED AMENDMENTS

Please amend the claims as follows in their marked form.

1. A composition for topical application to the skin comprising a mixture of [effective amounts of] cholesterol sulfate or salts thereof present in an amount between 0.05 to about 5.00 percent, and an exfoliant present in an amount between 0.1 to about 10.0 percent added to a cosmetically or pharmaceutically acceptable vehicle.

16. A method for improving or maintaining a healthy skin barrier which comprises adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent by weight of the composition, and from about 0.1 to 10.0 percent by weight of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof, and applying said vehicle containing said mixture to the skin.

18. The method of claim 1 in which the composition comprises about 0.05[4] to about 1.00 percent cholesterol sulfate.

19. A method of treating or reducing damage to the skin, wherein the damage is associated with a reduction or loss of skin barrier function, which comprises adding an effective amount of a mixture to a cosmetically or pharmaceutically acceptable vehicle wherein said mixture comprises cholesterol sulfate or salts thereof in an amount from about 0.05 to about 5.00 percent, and about 0.1 to about 10.0 percent of an amino sugar selected from the group consisting of N-acetyl-D-glucosamine, N-acetylgalactosamine, and a combination thereof by weight of the composition, and applying said vehicle containing said mixture to the skin.

Please cancel claim 2.